



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens (ID 3016, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2012.2852](https://doi.org/10.2903/j.efsa.2012.2852)

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2012). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens (ID 3016, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006*. European Food Safety Authority. the EFSA Journal Vol. 10(8) No. 2852 <https://doi.org/10.2903/j.efsa.2012.2852>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens (ID 3016, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and immune defence against pathogens. The food constituent that is the subject of the health claim, a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose, is sufficiently characterised. The claimed effect, contribution to immune defence against pathogens, is a beneficial physiological effect. The proposed target population is the general population. No human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim. On the basis of the data provided, the Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens.

© European Food Safety Authority, 2012

KEY WORDS

Lactobacillus helveticus CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426, fructo-oligosaccharides, pathogens, immune defence, health claims.

¹ On request from the European Commission, Question No EFSA-Q-2012-00204, adopted on 28 June 2012.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens (ID 3016, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(8):2852. [15 pp.]. doi:10.2903/j.efsa.2012.2852. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of a health claim in relation to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens. The scientific substantiation is based on the information provided by the competent Authority of France for further assessment of this claim.

The food constituent that is the subject of the health claim is a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose. The Panel considers that the combination *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose is sufficiently characterised.

The claimed effect, which is proposed for further assessment, is “helps to stimulate the immune system and thereby decreases the risk of occurrence of common infectious diseases”. The proposed target population is the general population. The Panel considers that contribution to immune defence against pathogens is a beneficial physiological effect.

One human intervention study was carried out with the combination of bacterial strains and fructo-oligosaccharides, that is the subject of the health claim, to assess the effect on the incidence of infections during a winter period in children who had suffered from at least three episodes of ear, nose and throat infections, other respiratory tract infections or gastro-intestinal infections in the previous winter. All health problems of any type were recorded by parents in a diary. The primary outcome was the percentage of children who suffered from at least one health problem of any nature during the intervention period. The Panel notes that no information was provided on the diagnostic criteria and on the validity of diaries used to assess the incidence of infections, and that the evidence provided did not establish that the outcome measures used in this study are appropriate measures of infections in the study population. The Panel also notes that no information has been provided in the publication about the use of rescue medication, which may have confounded the results and that different types of health problems were considered together. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

No human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens.

TABLE OF CONTENTS

| | |
|---|----|
| Abstract | 1 |
| Summary | 2 |
| Table of contents | 3 |
| Background as provided by the European Commission..... | 4 |
| Terms of reference as provided by the European Commission..... | 4 |
| EFSA Disclaimer..... | 4 |
| Introduction | 5 |
| Assessment | 5 |
| 1. Characterisation of the food/constituent (ID 3016)..... | 5 |
| 2. Relevance of the claimed effect to human health (ID 3016)..... | 6 |
| 3. Scientific substantiation of the claimed effect (ID 3016)..... | 6 |
| Conclusions | 7 |
| Documentation provided to EFSA | 7 |
| References | 7 |
| Appendices | 9 |
| Glossary and Abbreviations | 15 |

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be insufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ in which the Panel concluded that the data available were not sufficient to characterise a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium bifidum* CNCM I-3426 and *Bifidobacterium infantis* CNCM I-3424 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010), EFSA received additional information from the competent Authority of France for further assessment of this claim. The information provided in the framework of further assessment for the health claim which is the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 3016)

The food constituent that is the subject of the health claim is a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium infantis* CNCM I-3424 and *Bifidobacterium bifidum* CNCM I-3426 in the ratio of 6:2:2. The product also contains fructo-oligosaccharides (750 mg/sachet).

The strain *L. helveticus* CNCM I-1722 is also known as *L. helveticus* R0052. A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM I-1722) was provided. The CNCM is a restricted-access non-public collection, which has the status of an International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of *L. helveticus* CNCM I-1722 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile, PAGE) and genotypic (DNA-DNA hybridisation, 16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, AFLP, MLST, RAPD, PFGE) methods, were provided in the application for further assessment and in the accompanying references (Naser et al., 2006). The Panel considers that the strain *L. helveticus* CNCM I-1722 is sufficiently characterised.

The strain *B. infantis* CNCM I-3424 is also known as *B. infantis* R0033. A culture collection number from the CNCM, I-3424, was provided. The species *B. infantis* has been reclassified as a subspecies of *B. longum*, i.e. *B. longum* subsp. *infantis* (Mattarelli et al., 2008). Data on the identification and characterisation of *B. infantis* CNCM I-3424 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile) and genotypic (16S rRNA gene sequence analysis, elongation factor *tuf* gene sequence analysis, RAPD, PFGE) methods, were provided in the application for further assessment and in the accompanying references (Cazzola et al., 2010a). The Panel considers that the strain *B. longum* subsp. *infantis* CNCM I-3424 is sufficiently characterised.

The strain *B. bifidum* CNCM I-3426 is also known as *B. bifidum* R0071. A culture collection number from the CNCM, I-3426, was provided. Data on the identification and characterisation of *B. bifidum* CNCM I-3426 at species and strain level, by using both phenotypic (cell morphology, colony morphology, carbohydrate fermentation pattern, enzymatic activity profile) and genotypic (16S rRNA gene sequence analysis, elongation factor *tuf* gene sequence analysis, RAPD, PFGE) methods, were provided in the application for further assessment and in the accompanying references (Cazzola et al., 2010a). The Panel considers that the strain *B. bifidum* CNCM I-3426 is sufficiently characterised.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

From the references provided, the Panel assumes that the fructo-oligosaccharides (FOS) are obtained from sucrose. They are prepared by enzymatic elongation of sucrose, and consist of a mixture of kestose (glucose-fructose-fructose, GF2), nystose (GF3) and fructosyl nystose (GF4), with an average degree of polymerisation (DP_{av}) of 3.6, and are sometimes referred to as short-chain fructo-oligosaccharides. FOS from sucrose differ from natural fructans by degree of polymerisation (DP) (only 10 % of native chicory inulin have a DP between 2 and 5) (Roberfroid, 2007), and differ from oligofructose prepared by inulin hydrolysis (DP from 2 to 7, DP_{av} 4) by the presence of a glucose moiety.

The Panel considers that the food constituent, a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 3016)

The claimed effect, which is proposed for further assessment, is “helps to stimulate the immune system and thereby decreases the risk of occurrence of common infectious diseases”. The proposed target population is the general population.

The Panel assumes that the claimed effect refers to contribution to immune defence against pathogens. The Panel considers that contribution to immune defence against pathogens is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 3016)

The references provided in relation to the claim included one human study, one meta-analysis of human studies, animal studies, *in vitro* studies and general review articles. Of these references, many were not related to the combination of food constituents which is the subject of the claim, or they addressed characterisation aspects of the microorganisms. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human intervention study (Cazzola et al., 2010b) and one animal study (Cazzola et al., 2010a) were carried out with the combination which is the subject of the health claim, consisting of *L. helveticus* CNCM I-1722, *B. infantis* CNCM I-3424 and *B. bifidum* CNCM I-3426 in the ratio of 6:2:2, with a total bacterial count $\geq 3 \times 10^9$ CFU and 750 mg FOS from sucrose.

In a multicentre, randomised, double-blind, placebo-controlled, parallel intervention study, Cazzola et al. (2010b) assessed the effect of consumption of the combination of bacterial strains and fructo-oligosaccharides, which is the subject of the claim, during a winter period (December – March) on the incidence of infections in 135 children (mean age 4.1 ± 1.0 years) who had suffered from at least three episodes of ear, nose and throat infections, other respiratory tract infections or gastro-intestinal infections in the previous winter. The children were randomised in blocks of six to consume either the intervention (n=62) or the placebo (starch, n=73) for three months. All health problems of any type were recorded by parents in a diary. The primary outcome was the percentage of children who suffered from at least one health problem of any nature during the intervention period. Secondary outcomes comprised the percentages of children suffering from at least one health problem characterised by respiratory or gastro-intestinal symptoms, the percentage of children with at least one febrile episode, the number of reported health problems per included child, and the percentage of children with at least one health problem causing one or more days of school loss. The Panel notes that no information was provided on the diagnostic criteria and on the validity of diaries used to assess the incidence of infections, and that the evidence provided did not establish that the outcome measures used in this study were appropriate measures of infections in the study population. The Panel also notes that no information was provided in the publication about the use of rescue medication, which may have confounded the results and that different type of health problems were considered together. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

One animal study (Cazzola et al., 2010a) explored the mechanisms by which the combination of bacterial strains and fructo-oligosaccharides which is the subject of the claim could exert an effect on the response to infections by measuring serum levels of pro- and anti-inflammatory cytokines in a rat model. The Panel considers that in the absence of evidence for an effect on immune defence against pathogens in humans, evidence provided in this animal study cannot be used for the scientific substantiation of a claim on immune defence against pathogens.

The Panel notes that no human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose, which is the subject of the health claims, is sufficiently characterised.
- The claimed effect proposed for further assessment is “helps to stimulate the immune system and thereby decreases the risk of occurrence of common infectious diseases”. The proposed target population is the general population. Contribution to immune defence against pathogens is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of a combination of *L. helveticus* CNCM I-1722, *B. longum* subsp. *infantis* CNCM I-3424, *B. bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose and contribution to immune defence against pathogens.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00204). The scientific substantiation is based on the information provided by the competent Authority of France for further assessment of this claim (available at: <http://www.efsa.europa.eu/en/topics/topic/article13.htm>).

REFERENCES

- Cazzola M, Tompkins TA and Matera MG, 2010a. Immunomodulatory impact of a synbiotic in Th1 and Th2 models of infection. *Therapeutic Advances in Respiratory Disease*, 4, 259-270.
- Cazzola M, Pham-Thi N, Kerihuel JC, Durand H and Bohbot S, 2010b. Efficacy of a synbiotic supplementation in the prevention of common winter diseases in children: a randomized, double-blind, placebo-controlled pilot study. *Therapeutic Advances in Respiratory Disease*, 4, 271-278.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific opinion on the substantiation of health claims related to non-characterised microorganisms pursuant to Article 13 of Regulation (EC) No 1924/2006 on request from the European Commission. *EFSA Journal*, 8(2):1470, 44 pp.
- Mattarelli P, Bonaparte C, Pot B and Biavati B, 2008. Proposal to reclassify the three biotypes of *Bifidobacterium longum* as three subspecies: *Bifidobacterium longum* subsp. *longum* subsp. nov.,

Bifidobacterium longum subsp. *infantis* comb. nov. and *Bifidobacterium longum* subsp. *suis* comb. nov. International Journal of Systematic and Evolutionary Microbiology, 58, 767-772.

Naser SM, Hagen KE, Vancanneyt M, Cleenwerck I, Swings J and Tompkins TA, 2006. *Lactobacillus suntoryeus* Cachat and Priest 2005 is a later synonym of *Lactobacillus helveticus* (Orla-Jensen 1919) Bergey et al. 1925 (Approved Lists 1980). International Journal of Systematic and Evolutionary Microbiology, 56, 355-360.

Roberfroid MB, 2007. Inulin-type fructans: Functional food ingredients. Journal of Nutrition, 137, 2493s-2502s.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁵ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁶

Foods are commonly involved in many different functions⁷ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

⁵ OJ L12, 18/01/2007

⁶ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁷ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Health claims related to a combination of *Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* subsp. *infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426 and fructo-oligosaccharides from sucrose, including conditions of use, as proposed in the framework of further assessment.

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|------|--|--|---|
| 3016 | <p><i>Lactobacillus helveticus</i> CNCM I-1722, <i>Bifidobacterium infantis</i> CNCM I-3424 and <i>Bifidobacterium bifidum</i> CNCM I-3426</p> <p>The percentage of each strain is respectively 60%, 20% and 20% in the form of lyophilised powder.</p> <p>The finished product is commercialised as a blend of the above-mentioned strains and fructooligosaccharides (750 mg / sachet) under the brand name Probiokid.</p> | Probiokid helps to stimulate the immune system and thereby decreases the risk of occurrence of common infectious diseases. | <p>Participates in healthy microflora balance essential for body's natural defences.</p> <p>Stimulates the specific and non specific immune system.</p> <p>Reinforces the barrier effect against pathogens.</p> <p>Reinforces the body's protection against infections.</p> <p>Strengthens the body's natural defences.</p> <p>Probiotic to benefit health and/or to confer a health benefit.</p> |
| | <p>Conditions of use</p> <p>The recommended dosage is 1 sachet of Probiokid per day for 3 months.</p> <p>The target population is the general population.</p> | | |

GLOSSARY AND ABBREVIATIONS

| | |
|------|---|
| AFLP | Amplified fragment length polymorphism |
| CNCM | Collection Nationale de Cultures de Microorganismes, France |
| CFU | Colony forming units |
| DNA | Deoxyribonucleic acid |
| DP | Degree of polymerisation |
| FOS | Fructo-oligosaccharides |
| MLST | Multilocus sequence typing |
| PAGE | Polyacrylamide gel electrophoresis |
| PFGE | Pulsed field gel electrophoresis |
| RAPD | Random amplified polymorphic DNA |
| RNA | Ribonucleic acid |